



THE UNITED STATES PATENT AND TRADEMARK OFFICE

~~In the Patent Application of~~

Thorsteinn LOFTSSON et al.

Application No.: 10/750,940

**Filed: January 5, 2004**

For: HIGH-ENERGY CYCLODEXTRIN  
COMPLEXES

Group Art Unit: 1623

**Examiner:**

Confirmation No.: 2037

## **FIRST INFORMATION DISCLOSURE STATEMENT**

**Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**Sir:**

In accordance with the requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98, applicants are submitting herewith a Form PTO-1449 substitute (two sheets) listing documents for consideration by the Examiner.

All of the listed documents were previously made of record in prior Application Serial No. 09/250,185, filed February 16, 1999, upon which Applicants rely for the benefits provided in 35 U.S.C. § 120. In accordance with 37 C.F.R. § 1.98, further copies of these documents are not required to be filed herein.

This statement and accompanying Form PTO-1449 substitute are being submitted together with the Missing Parts and thus before the first Office Action on the merits. Since these documents are being filed within the time period set forth in 37 C.F.R. § 1.97(b), no fee or statement is required.

It is respectfully requested that this Information Disclosure Statement be acknowledged and that a copy of applicants Form PTO-1449 substitute (2 sheets) be returned to the undersigned with the next official communication.

Respectfully submitted,

**BURNS, DOANE, SWECKER & MATHIS, L.L.P.**

Date May 21, 2004

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# **FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(use as many sheets as necessary)

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of

2

**Complete if Known**

Application Number	10/750,940
Filing Date	January 5, 2004
First Named Inventor	Thorsteinn LOFTSSON et al.
Examiner Name	
Attorney Docket Number	016914-039

MAY 21 2004

**U.S. PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Issue/Publication Date (MM-DD-YYYY)
	5,134,127	A	Stella et al.	07-28-1992
	5,324,718		Loftsson	06-28-1994
	5,376,645		Stella et al.	12-27-1994
	5,472,954		Loftsson	12-05-1995

**FOREIGN PATENT DOCUMENTS**

Examiner Initials	Document Number	Kind Code (if known)	Country	Date of Publication (MM-DD-YYYY)	Translation	
					Yes	No
	94/02518		WO	02-03-1994		

**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Oh et al, <i>International Journal of Pharmaceutics</i> , 73, pp. 23-31 (1991).
	Loftsson and Brewster, <i>Pharm. Technol. Eur.</i> , 9(5), 26-34 (May 1997).
	Loftsson and Brewster, <i>J. Pharm. Sci.</i> , 85(10), 1017-1025 (October 1996).
	Rajewski and Stella, <i>J. Pharm. Sci.</i> , 85 (11), 1142-1169 (November 1996).
	Irie and Uekama, <i>J. Pharm. Sci.</i> , 86(2), 147-162 (February 1997).
	Stella and Rajewski, <i>Pharm. Res.</i> , 14(5), 556-567 (1997).
	Loftsson, <i>Pharmazie</i> , 53, 733-740 (1998).
	Frömming and Szejtli, <i>Cyclodextrins in Pharmacy</i> , Kluwer Academic Publishers, Dordrecht, The Netherlands, pp. 105-107 (1994).
	Loftsson and Ólafsson, <i>Int. J. Dermatol.</i> , 37, 241-246 (1998).
	Loftsson and Stefánsson, <i>Drug. Dev. Ind. Pharm.</i> , 23 (5), 473-481 (1997).
	Loftsson, Másson and Stefánsson, "Cyclodextrins as Permeation Enhancers", <i>Proceedings of the 17<sup>th</sup> Pharmaceutical Technology Conference and Exhibition</i> , volume 2, Dublin, pp. 313-324 (24-26 March 1998).
	Schwartz, Rhodes and Cooper, <i>J. Pharm. Sci.</i> , 66, 994-997 (July 1977).
	Loftsson and Bodor, <i>Acta Pharm. Nord.</i> , 1, 185-194 (1989). (Issue No. 4).
	Loftsson and Sigurdardóttir, "Cyclodextrins as skin penetration enhancers", in J. Szejtli and Szenté (eds), <i>Proceedings of the Eighth International Symposium on Cyclodextrins</i> , Kluwer Academic Publishers, pp. 403-406 (1996).

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M.P.E.P. § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

Substitute for form 1449A/PTO & 1449B/PTO				<b>Complete if Known</b>	
<b>FIRST INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/750,940
				Filing Date	January 5, 2004
				First Named Inventor	Thorsteinn LOFTSSON et al.
				Examiner Name	
Sheet	2	of	2	Attorney Docket Number	016914-039

### NON-PATENT LITERATURE DOCUMENTS

Examiner Initials	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	Roth, Eger and Troschütz, <i>Pharmaceutical Chemistry</i> , Volume 2: Drug Analysis, Ellis Horwood, pp. 308-309 (1991).
	Gerecke, <i>Br. J. Clin. Pharmac.</i> , 11S-16S (1983).
	<i>Pharmaceutical Chemistry, Volume 2: Drug Analysis</i> , ed. H.J. Roth et al., pp. 302-311; 496-513; 518-525; 546-547; 580-581; 590-591; 594-597; 659-673; published by Ellis Horwood, London (1988).
	<i>Chemical Stability of Pharmaceuticals, A Handbook for Pharmacists</i> , Second Edition, ed. Kenneth A. Connors et al, pp. 257-263; 675-684; 764-773; published by Wiley-Interscience; John Wiley & Sons, New York (1986).
	Stenlake, <i>Foundations of Molecular Pharmacology, Volume 1, Medicinal and Pharmaceutical Chemistry</i> , pp. 512-513, published by The Athlone Press, University of London (1979).
	Junquera et al, <i>J. Org. Chem.</i> , 63, pp. 4349-4358 (1998). (WWW publ.: 06/11/98).
	Li et al, <i>Journal of Pharmaceutical Sciences</i> , 87, No. 12, pp. 1535-1537 (December 1998).
	Krishnamoorthy et al., "Complexation of Weak Acids and Bases with Cyclodextrins: Effects of Substrate Ionization and the Estimation and Interpretation of Association Constants," <i>International J. of Pharmaceutical Advances</i> , 1 (3), 330-343 (Jan., 1996).
	Loftsson et al., "Effects of 2-Hydroxypropyl-β-cyclodextrin on the Aqueous Solubility of Drugs and Transdermal Delivery of 17-β-Estradiol," <i>Acta Pharm. Nord.</i> 1 (4), 185-194 (1989).
	Menard et al., "Studies on the Effect of pH, Temperature and ring Size on the Complexation of Phenytoin with Cyclodextrins," <i>Pharm. Acta Helv.</i> , 63 (11), 303-308 (1988).
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	Selva et al., "Study of the Salts of Organic Hydroxy Acids of the Terfenadine β-Cyclodextrin Complex in Solution of Mass Spectrometry," <i>Journal of Mass Spectrometry</i> , 30 (1), 219-220 (1995).
	Fenyvesi et al., "Enhancement of the Drug Solubilizing Capacity of Hydroxypropyl-β-cyclodextrin by Ternary Complex Formation," in <i>The 7<sup>th</sup> Cyclodextrin Symposium</i> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 414-418.
	Vikmon et al., "Terfenadine/Cyclodextrin/Hydroxyacid Multicomponent Complexes," in <i>The 7<sup>th</sup> Cyclodextrin Symposium</i> , T. Osa (ed.), Business Center for Academic Societies Japan, Tokyo, Japan, 1994, pages 480-483.

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